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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/340,338 | 06/25/1999 | SPIROS FOTINOS | 1581/120 | 3768 |

25561 7590 07/22/2004

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EXAMINER

SPEAR, JAMES M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/340,338 | FOTINOS, SPIROS | |
| | Examiner | Art Unit | |
| | James M Spear | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-103 is/are allowed.
- 6) ☒ Claim(s) 42,43,47,48 and 50-56 is/are rejected.
- 7) ☒ Claim(s) 44-46 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20 November 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 42, 43, 47, 48, and 50-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Denzer US 6,007,836. The claims are rejected for the reasons set forth in Paper No. 27, mailed June 18, 2003. For claims 52-54 the reference clearly shows plasticizers such as polyethylene glycol, triacetin, and propylene glycol to maintain the desired degree of flexibility. See column 8, lines 40-52. Applicant feel that since the rejected claims describe a device that does not include a backing layer and Denzer shows a backing layer the rejection should be withdrawn. It is the position of this office that Denzer describes applicant's particular device and the layers are carriers that facilitate storage and transport but are of no consequence to the particular composition when in use. Once in use the layers are removed. Column 12, lines 13-24. How the composition is made be it with or without barrier layers is not a basis for determining patentability of composition claims. Applicants state that examining Denzer in greater detail, one observes the critical importance ascribed in the Denzer specification to keeping the medicament of the patch away from the second sex partner. However these arguments are directed to a method of use, while applicant's claims are to a composition. The scope of applicant's claims clearly read on the composition disclosed in the prior art of record.
3. Claims 44-46 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 57-103 are allowed.

Claims 42, 43, 47, 48 and 50-56 are rejected.

Claims 1-41 have been canceled.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kanakaris et al US 6,589,990 B1 shows a misoprostol formulation for topical application as a gel for erectile dysfunction that may be of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JAMES M. SPEAR
PRIMARY EXAMINER

AU 1615

7-16-04